UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 15 2008

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

James H. Lecky, Director
Office of Protected Resources
United States Department of Commerce
National Oceanic and Atmospheric Administration
National Marine Fisheries Service
Silver Spring, MD 20910

Dear Mr. Lecky:

Through this letter we are relaying EPA's comments on the National Marine Fisheries Service (NMFS) July 31, 2008 Draft Biological Opinion (the "Draft") relative to the potential effects of pesticides containing chlorpyrifos, diazinon, and malathion, to federally listed threatened or endangered Pacific salmon and steelhead and their critical habitat, if designated. Receipt of the July 31, 2008 Draft Biological Opinion was our first opportunity to see how NMFS would approach assessing whether a pesticide registration action would jeopardize the continued existence of a listed species. Because this was our first opportunity to review NMFS approach, and given the short time frame in which we were requested to comment, our comments do not contain a detailed point-by-point review of the Draft. Nonetheless we are providing comments that address both scientific and process/policy issues related specifically to the Draft, but that also may be applicable to the future development of other biological opinions by NMFS.

The Draft lacks a level of transparency necessary for EPA to understand NMFS' rationale for its opinion that the use of any of these pesticides will jeopardize the continued existence of any of the species at issue. It is generally not transparent as to what methodology NMFS employed to collect information beyond that which was provided by EPA in the consultation packages nor is it clear how NMFS selected some available information for use in its assessment to the exclusion of other available data. It also is unclear how NMFS undertook specific analyses and how NMFS integrated or reconciled apparently conflicting information.

While your transmittal letter requested that we jointly discuss reasonable and prudent alternatives (RPAs) to prevent likely jeopardy, it is difficult for us to meaningfully engage in such a discussion at this time. First, we have serious questions and doubts about the support for NMFS' conclusion that these three pesticides jeopardize all of these species and adversely modify their critical habitat. Second, the Draft provides no basis from which to have a meaningful discussion of RPAs since it fails to identify a level of exposure to these pesticides that would *not* result, in NMFS opinion, in jeopardy to the species. Without a target level of exposure, there could be no basis for agreement between our agencies that any alternative was either necessary or appropriate.

Given these broad concerns relative to the Draft, and our more specific input noted below, it is our expectation that NMFS will provide an additional review opportunity on a revised Draft Biological Opinion, prior to issuance of a final Biological Opinion.

- **Status of species within Evolutionarily Significant Units** - While each Evolutionarily Significant Unit (ESU) or Distinct Population Segment (DPS) is listed separately with its own designation of threatened or endangered, the Draft seems to draw conclusions on a species level rather than addressing risks to specific ESUs or DPSs. Similarly, the broad conclusion in the Draft of variable local reductions in the conservation value of critical habitat does not address whether a given designated critical habitat would no longer support the recovery of a given ESU.

  The conclusions in the Draft also appear to be made without regard to the status of the ESUs or DPSs. Most of the ESUs or DPSs are considered threatened and in some cases, those designations were re-confirmed as recently as 2005, during a status review. In reviewing the status and trends sections in the Draft, it appears as though some ESUs or DPSs have an increasing number of spawners rather than a decline, and others have fluctuated widely over the course of the past decade declining to low numbers and then rebounding to high numbers. Use of these pesticides has been ongoing for decades and has actually declined over the past several years. If the threatened status of the species has not changed appreciably during this considerable period, it would appear to provide some indication that use of these pesticides are not appreciably reducing the likelihood of both survival and recovery of these ESUs and DPSs -- which is the standard for jeopardy -- yet the draft makes no effort to address this empirical evidence. Additionally, the Draft makes no mention of the fact that agriculture chemicals are secondary stressors and therefore are considered to be a minor factor in species survival relative to other factors. In any case, given this fact pattern, it is difficult to see how a conclusion could be reached that use of these pesticides jeopardizes the continued existence of all 28 ESUs or DPSs of Pacific Salmon and Steelhead.

- **Actions on which EPA initiated consultation** – The Draft mischaracterizes the Actions on which EPA initiated consultation, both specifically and broadly. First, the Draft is not consistent in describing the findings in EPA's consultation packages. In some cases the Draft notes the ESUs for which EPA found No Effect but in other cases fails to acknowledge those findings. Our assessment for malathion found *No Effect* for the California Coastal Chinook Salmon and the Northern California Steelhead for both residential and non-residential uses and we did not initiate consultation on these two findings. Similarly for chlorpyrifos, there were two ESUs for which EPA found *No Effect* and for which we did not initiate consultation (the Columbia River Chum and the Ozette Lake Sockeye Salmon). Also, the Draft includes two ESUs listed since initiation of consultation, for which EPA has not had an opportunity to provide its assessment to NMFS and on which EPA did not initiate consultation. It is unclear to EPA why NMFS chose to include the "no effect" determinations and new listings in the Draft, rather than requesting that EPA initiate consultation on these matters, as NMFS regulations contemplate. These matters are beyond the scope of NMFS litigation regarding its current consultations with EPA, so there would appear to be no compelling reason for NMFS to forego the appropriate regulatory process in this case. EPA believes the Draft should be limited to the actions on which we initiated consultation.

  The Draft also appears to reflect a misunderstanding of currently labeled uses in spite of the fact that it acknowledges mitigations EPA put in place to reduce potential exposure and

which are reflected in Interim Reregistration Eligibility Decision (IRED) documents and Reregistration Eligibility Decision (RED) documents in the possession of NMFS. EPA's consultation packages for both chlorpyrifos and diazinon, in fact, included the label mitigation set forth in the IREDs which have been approved for all new production of these products. We understand your concern that some existing stocks of old product may still exist in the hands of users and that you may therefore want to address these existing stocks in the your Biological Opinion. However, EPA does not understand why the Draft did not also address the impact of the label mitigation in the IREDs. It seems to be a poor use of both our agencies' resources to limit the scope of this consultation to addressing only old product labels rather than currently approved labeling.

- **Assumptions** - There appear to be multiple assumptions throughout the Draft about the significance, or lack thereof, of a pesticide label relative to its use. For example, the Draft appears to assume that if an application scenario is not specifically excluded on the label, it should be assessed as part of the Action. For instance, the Draft evaluates direct overspray to water bodies for chlorpyrifos even though it acknowledges this would be a misuse. Misuse of a pesticide is an unlawful act, is not a component of the federal Action and therefore should not be evaluated as such. The Draft also assumes risk from the use of all three pesticides at their maximum application rates at the same location and time, because such practice is not prohibited on the label. The Draft does not provide analyses that establish the extent to which this assumption is realistic or reasonable, nor does the Draft articulate to what extent the finding of jeopardy is dependent upon this assumption.

- **Data used in the Draft** - The Draft seems to draw conclusions based on a body of data that fails to include certain studies and information provided by EPA in its consultation package while including other information. There seems to be no explanation of the criteria that were used to determine what information was included or excluded. For example, it does not appear that NMFS considered the considerable information provided in our consultation packages regarding actual usage of these pesticides in CA and WA, the timing of use, or the locations on which these pesticides are used. Further, much of the historical water quality monitoring data relied upon is outdated and inappropriate in the context of the use of these pesticides. These historical data more appropriately reflect pesticide use prior to substantive mitigation that has been put in place by EPA.

- **Modeling and monitoring** – Some monitoring data are used in the Draft to demonstrate that the predicted exposure values in EPA's modeled assessments do not reflect possible exposures to salmonids. Some of these monitoring data however, represent edge of field runoff values and the specific relevance of these data to salmon habitat is not established in the Draft.

  The Draft contemplates direct pesticide overspray as a potential exposure scenario in off-channel habitats. In addition to direct overspray being an illegal use and not part of the Action, the exposure modeling tables in the Draft present instantaneous concentrations in water, for applications as high as 10 lbs/acre. The Draft does not document how NMFS determined this high application rate could be assumed from the labels of the three pesticides. It is not clear how such high application rates were derived for all uses of all three chemicals. The Draft uses the AgDrift model to estimate mosquito adulticide

applications which appear to be based on 10-meter or less application heights and fine to very-fine droplet spectra. However, this is inconsistent with aerially applied mosquito adulticide practices that use ULV (ultra-low volume) applications at up to 100 meters or more in height.

The population model employed by NMFS assumes a range of concentrations over a four-day averaging period. It is not clear on what NMFS is basing its assumption that these types of exposures, particularly at the high end of the Draft's exposure assumptions (e.g., 5.0, 10.0, or 100.0 ppb), are present for four days. It is more likely that the peak concentrations detected from monitoring decline over this period of time. However, if there are data that support the assumption, they should be provided in the Draft. If there are no such data, that too should be made clear. Furthermore, the spatial and temporal relevance of these exposure values is not explained. This is significant because the NMFS model results indicate that at the lower exposures assessed, typically at 1 - 2 ppb over a four day period, there is no population-level effect. This raises a question about the underlying assumptions in the population modeling. It appears to be assumed that a significant number of individuals are expected to be exposed to the concentrations evaluated in tables 52 to 55. This seems unreasonable, particularly at the higher exposures, given the infrequency of those concentrations in the monitoring data sets. The Draft however, provides no explanation of how NMFS' assumptions can be characterized as realistic or reasonable.

There are numerous areas in Appendix 1 which describes NMFS population modeling, where the methods, underlying data, assumptions, and calculations are not transparent. Neither EPA nor the public can reproduce the findings of these modeling efforts using the information presented in the Draft. For example:

- Duration of the population model – it is unclear for how many life cycles the population model was run to obtain the results presented in the Draft.
- Periodicity of exposure – it is unclear how often individuals are assumed to be exposed to the concentrations of the chemicals used in the model.
- Proportions of individuals exposed – it appears that all individuals are assumed to be exposed at the concentrations of the chemicals used in the model. Does this mean all individuals in a given age class, a given ESU, a given stream, or a given stream reach?
- Figures 2 and 3– these figures present the relationships used to link anticholinesterase exposure to food acquisition behavior. The figures present a series of curves but do not present the underlying mathematical description of each curve nor the mathematics used to link them together (i.e., the actual mathematical model).
- Tables 1, 2 and 4 there are no indications of the underlying sources for the values selected in these tables. Also the description of the model provides no insight as to how the values for error or sensitivity in any of the tables were used in and derived from the model, respectively. It is also unclear why some values have error terms and others are essentially viewed as constants.
- Exposure durations – it appears that the model assumes a four-day average exposure. Is this assuming that all individuals everywhere at some point in their life cycle are exposed to a constant concentration over four days? Given the response of the model at low levels, the Draft should include a discussion of how an assumption of constant low-dose exposure affects the model conclusions?

The consideration of additivity in the Draft appears to group maximum concentrations of each assessed chemical as a co-occurring value with the other maxima. If these co-occurrences are actually happening, it would be appropriate for the Draft to state when and where these maxima co-occurrences have been demonstrated. EPA would expect that these occurrences would be quite rare, but no consideration is given to the actual frequency of such an event. For example, Table 51 shows NAWQA maxima selected from four States as occurring simultaneously in one water body. However, given that 4000 samples were included in this analysis, the probability of this co-occurrence should be presented in the Draft. Without knowing the locations of these measurements and the dates of sampling, there appears to be no basis to conclude that such effects are "reasonably likely to occur" as a consequence of the Actions being assessed. The Draft suggests that such combinations of temporally and spatially separated events is appropriate and cites as support the GENEEC estimate scenario for simultaneous use of all three pesticides on a single onion field. "We found no restrictions that would prevent co-application or sequential application of chlorpyrifos, malathion or diazinon". While the labels do not preclude such possibilities the actual likelihood that three broad spectrum insecticides would be used at maximum rates at the same time on a given field has not been discussed in the Draft.

- **Lack of spatial or temporal analyses** – Clearly NMFS is concerned about vulnerable habitats beyond those typically addressed in EPA's exposure assessments. Prominent among these vulnerable habitats are what are generically described as "off-channel" habitats. The Draft provides references that indicate the importance of these habitats to salmonids but these references in general, appear to be lacking detail of the spatial and temporal relevance of these habitats. There seems to be an assumption that these habitats are more vulnerable and likely to have higher exposures than those indicated in EPA's assessments however, this assumption is not supported by any data and supporting analyses. In addition to missing data regarding the spatial and temporal relevance of these habitats to individual species and populations, also missing are any monitoring data to support the contention that the exposure estimates provided for these habitats are reasonable.

  The analysis for both individual effects and population level effects appear to be done generically and not on an individual ESU basis. This suggests that the *jeopardy* determination is based on an assumption that some significant number of individuals of a given species are subject to the various exposures evaluated in the Draft. The assumptions in the population modeling as to how many individuals are exposed, how frequently they are exposed, and what times of year they are exposed relative to pesticide use is not provided and therefore it is not possible to review the scientific basis of the Draft's conclusion. There is no spatial or temporal analysis that relates the exposure evaluated to the species. Further, consideration of the spatial and temporal aspects of pesticide use appear to have been discounted in the Draft, and instead, there are assumptions made that pesticide use is consistent throughout each watershed within the action area. The Draft also seems to include the assumption that every water body in every watershed within the four States, is a salmon-supporting water body and that use of all three pesticides around salmon supporting waters will be the same throughout the watershed and the same throughout all the watersheds. EPA understands that substantial effort has been expended in Washington and Oregon to identify

specific streams and rivers that support listed salmonids and these specific water bodies comprise a fraction of the stream network in those states.

- **Metabolites, degradates, and other ingredients** – The Draft states that the presence of malathion monocarboxylic acid (MCA) in fish tissue suggests bioaccumulation by salmon. However, the Draft fails to discuss that the same study showed approximately 73%, 96%, and 96% of the radioactivity depurated by day 28 from the edible, whole, and non-edible portions of fish, respectively. This would be consistent with the profile for a carboxylic acid that would be readily conjugated and excreted, and consistent with the rapid metabolism of malathion in fish. The Draft's conclusion on bioaccumulation in this instance contradicts established definitions and concepts within the scientific community for processes and terminology concerning bioaccumulation. The Draft offers no explanation or rationale as to why commonly accepted scientific principles and concepts are not being applied in this instance.

  The Draft presents stream chemical analysis data showing the presence of nonylphenol (NP) and nonylphenol ethoxylate surfactants in surface waters. It appears as though the authors are suggesting that the presence of these surfactants might be largely or solely linked to use of the pesticides in question. However, these surfactants are used for a variety of industrial, commercial, and household purposes and the omission of a meaningful discussion of these possible origins of these chemicals in water serves to overstate the role that the registrations of chlorpyrifos, diazinon, and malathion may play in contributing to concentrations of these surfactants in water.

Thank you for providing the Draft for our review and input. As our comments make clear, we do not believe the available data supports NMFS' draft jeopardy conclusions. Given the significant nature of our comments, I request EPA be provided further opportunity to discuss the Draft with you and to review and comment on a revised Draft Biological Opinion and any Reasonable and Prudent Alternatives and/or Measures prior to NMFS issuing their final Opinion in this matter. Please let me know if you have any questions regarding this input. I look forward to successfully concluding consultation on these three federal Actions.

Sincerely,

Debra Edwards

Debra Edwards, Director
Office of Pesticide Programs

cc: Donald Brady
Arty Williams
Steven Bradbury